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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,031	03/02/2004	Kenneth C. Kennedy II	10000/303	1370

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BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, IL 60610

EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	**PAPER NUMBER**
3767	

MAIL DATE	DELIVERY MODE
04/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,031	KENNEDY ET AL.	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/05/2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. In the reply filed on February 5, 2008, claims 1, 7-9, and 12 were amended for minor informalities.

2. Claims 26-32 (Species B) were withdrawn based on the election of Species A (claims 1-25) in the election of species requirement.

3. Replacement drawing sheets 1-5 were provided for Figures 1-9.

4. Currently, claims 1-25 are being examined.

Election/Restrictions

5. Applicant's election of Species A (claims 1-25) with traverse during the teleconference with Michael Milz on July 23, 2007, is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, in the reply filed on February 5, 2008, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Response to Arguments

6. Applicant's arguments, see page 12, lines 11-31 to page 13, lines 1-15, filed February 5, 2008, with respect to the rejection(s) of claim(s) 1 under 35 USC 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Miraki (US 5,318,535).

Claim Objections

7. Claims 12 and 15 are objected to because of the following informalities:

In regards to claim 12, in line 4, the recitation of "member with **the to** the axis of the" should be changed to "member with the axis of the".

In regards to claim 15, the limitation that the "cannula [is] configured to slidingly engage an **exterior** surface of the sleeve" appears to be incorrect, since the cannula has an interior cross-sectional area that is less than the interior cross-sectional area of the sleeve. The specification states on page 16, that "In the embodiment illustrated in Fig. 8, a collar or cannula [188] is disposed inside the sleeve"; therefore, it does not make sense for the cannula to engage an exterior surface of the sleeve, as recited in the claim. The cannula should slidingly engage an **interior** surface of the sleeve.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 12 recites the limitation "the distal end [of the catheter] being in sliding engagement with the stiffening member" in reference to preceding claim 9. Claim 9 refers to preceding claim 8, in which it is stated that "the proximal end of the proximal portion of the stiffening member is fixedly connected to the proximal end portion of the catheter." If the stiffening member is fixed with respect to the catheter, as required of claim 8, then it is not

possible for the catheter to be in slidable engagement with the stiffening member, as required of claim 12. There is insufficient antecedent basis for this limitation in the claim. Claim 12 may properly depend from claim 1.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 7, 12-16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki (US 5,318,535).

In regards to claim 1, Miraki teaches a balloon catheter (Figures 5-7, balloon catheter [10]) comprising:

a. a inflatable balloon (balloon [132]) comprising a balloon wall (side wall [136]) defining an interior volume, the balloon further comprising a distal end, a proximal end (*labeled in Figure 6 below)*, and a central portion disposed therebetween

b. a catheter (shaft [32]) comprising a distal end portion (*labeled in Figure 6 below)* and a proximal end portion (*labeled in Figure 5 below)*, the proximal end portion comprising a connector (Y-connector [118]) configured to engage an inflation device (column 8, lines 50-56), the distal end portion fixedly connected to the proximal end of the balloon due to bond [130] (column 8, line 68 to column 9, lines 1-2), and a lumen (*labeled in Figure 6* below) extending though the catheter along an axis thereof and in

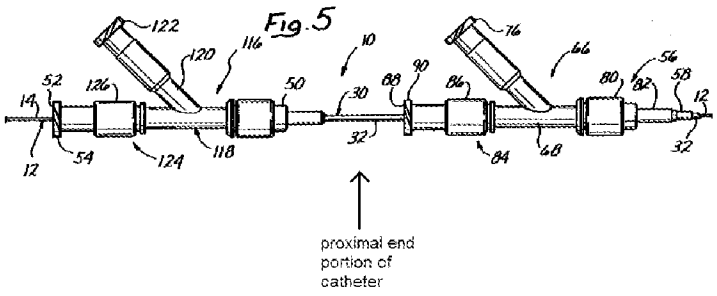
fluid communication with the interior volume of the balloon via bore [36][36'] (column 9, lines 12-16)

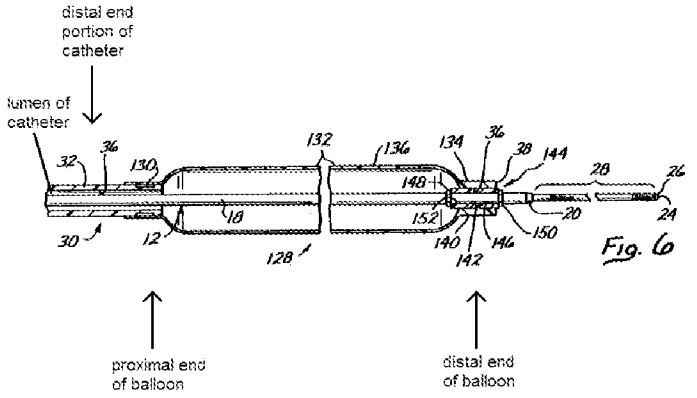
c. a stiffening member (guide wire assembly [12]) extending distally from the distal end portion of the catheter and through the interior volume of the balloon, the stiffening member being non-fixedly connected to the distal end of the balloon via the releasable engagement of collar [146] of stiffening member [12] and seal section [134] of balloon [132] (column 9, lines 2-4)(column 9, lines 25-32),

d. wherein movement of the distal end of the balloon relative to the proximal end of the balloon is not restrained by the catheter, *since the proximal end of the balloon is the only portion of the balloon that is attached to the catheter*

e. wherein axial movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally parallel to the axis of the catheter is not restrained by the stiffening member, *since the stiffening member [12] is non-fixedly connected to the distal end of the balloon* (column 9, lines 2-4)(column 9, lines 25-32) *and the stiffening member is axially movable* (Figure 6 to Figure 7)

f. wherein transverse movement of the distal end of the balloon relative to the proximal end of the balloon in a direction generally perpendicular to the axis of the catheter is restrained by the stiffening member, *since the presence of the stiffening member within the interior volume of the balloon prevents the balloon wall from completely moving inwards in the transverse direction upon deflation (Figure 7).*





In regards to claim 7, Miraki teaches that the stiffening member [12] comprises a proximal portion (proximal end portion [14]) extending along and generally parallel to the axis of the catheter [32] (Figure 5).

In regards to claim 12, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon [132] (Figure 6), the distal end being in sliding engagement (Figure 6 to Figure 7) with the stiffening member [12] so as to align the stiffening member with the axis of the catheter and naturally prevent significant transverse movement of the stiffening member in a direction generally perpendicular to the axis

of the catheter due to the closeness of the stiffening member to the inner wall of the catheter in the "distal end portion of catheter" labeled above in Figure 6.

In regards to claim 13, Miraki teaches that the distal end of the balloon [132] comprises a sleeve (cylindrical seal section [134]), a distal end of the stiffening member [12] being slidably disposed within the sleeve (Figure 6 to Figure 7).

In regards to claim 14, Miraki indirectly teaches that the sleeve [134] is spaced away from the distal end of the stiffening member [12] so as to permit axial movement of the distal end of the stiffening member relative to the sleeve (Figure 6 to Figure 7) *since in order for the stiffening member to be slidable within the sleeve, there must be some space/lumen within the sleeve within which the stiffening member can axially move.*

In regards to claim 15, Miraki teaches that the stiffening member [12] has a cannula (collar [146]) configured to slidingly engage an interior surface of the sleeve [134], with the cannula having an interior cross-sectional area that is less than an interior cross-sectional area of the sleeve (Figure 6-7). Concerning the limitation that the sleeve comprises a cannula disposed therein, when the cannula [146] engages with the sleeve [134] in a friction fit, the cannula is disposed within the sleeve (column 9, lines 25-32).

In regards to claim 16, Miraki teaches that the distal end of the stiffening member [12] comprises a retaining portion (retaining rings [148][150]) having an exterior cross-sectional area that is greater than the interior cross-sectional area of the cannula [146] (Figure 7) so as to prevent the distal end the stiffening member from passing through the cannula (column 9, lines 36-43).

In regards to claim 19, Miraki inherently teaches that an inflation device is connected to the connector [118] on the proximal end portion of the catheter with the statement that "a treatment fluid [is allowed] ... to be introduced via the luer fitting [122] of Y-connector [118] (column 10, lines 55-60).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki.

In regards to claim 17, Miraki teaches that the retaining portion (retaining rings [148][150]) comprises rings affixed to the distal end of the stiffening member [12], the rings having an outer diameter that is greater than the inside diameter of the cannula [146]. As required by claim 17, Miraki does not teach that the retaining portion is a rounded bead, as Miraki teaches rings. At the time the invention was made, it would have been an obvious matter of design choice to a person having ordinary skill in the art to shape the retaining rings of Miraki as rounded beads because Applicant has not disclosed that a rounded bead, as compared to a ring, provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with retaining rings as opposed to a retaining bead because both retaining structures perform the same function of prevention the stiffening member from passing through the

cannula. Therefore, it would have been an obvious matter of design choice to modify Miraki to obtain the invention as specified in claim 17.

14. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, as applied to claim 1 above, and further in view of Mulder (US 5,700,242).

In regards to claims 2-4, though Miraki is silent about the balloon's axial length being different in the three following states: deflated state, fully inflated state, and partially inflated state. Mulder teaches a balloon catheter with a balloon that is shortened longitudinally, in the axial direction, when it is inflated (column 2, lines 42-51). Therefore, as the balloon is inflated, the axial length decreases, which means that the deflated axial length, the partially inflated axial length, and the fully inflated axial length would all be different. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Mulder to those of Miraki in order to facilitate greater radial expansion of the balloon, without deflecting the tip of the balloon catheter, as the axial length of the balloon decreases with inflation of the balloon (column 2, lines 39-44).

In regards to claim 5, Miraki is silent about the material comprising the balloon wall. Mulder teaches that the balloon is made of an inelastic material (column 2, line 28). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the balloon material of Mulder to the balloon taught by Miraki because Mulder divulges that the use of their material allows for the calculation of the maximum radial diameter that the balloon can inflate to, as further inflation past this maximum radial diameter can cause buckling

of the inner catheter shaft, which would deflect the tip of the balloon catheter (column 2, lines 27-37).

15. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, as applied to claim 1 above, and further in view of Weber et al (US 2003/0130716).

In regards to claim 6, Miraki teaches that the balloon [132] is folded and over wrapped on itself in the deflated condition (column 9, lines 5-8); however, Miraki is silent about whether said folding involves axially oriented creases or pleats to facilitate the radial compression of the balloon to the deflated condition. Weber et al teaches that it is common practice to form a number of axially oriented wings in the wall of a balloon and fold the wings down along the side of the balloon (page 2, paragraph [0011]; Figure 2, longitudinal wings [6]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the axially oriented creases or pleats taught by Weber et al to the balloon of Miraki because Weber et al teaches that such folding of the creases or pleats helps to minimize the diameter of the deflated balloon (page 2, paragraph [0011]).

16. Claims 8-10, 21-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, as applied to claim 7 above, and further in view of Goodin (US 5,425,712).

In regards to claim 8, Miraki teaches that the proximal portion [14] of the stiffening member [12] is disposed within the lumen of the catheter [32] (Figure 5); however, Miraki does not teach that the proximal end of the proximal portion of the stiffening member is fixedly connected to the proximal end portion of the catheter, since the stiffening member is slidable

within the catheter (Figure 6 to Figure 7). Goodin teaches a balloon catheter with a stiff inner tube with a proximal end that is securely attached to the proximal end of a catheter via a branched hub (column 3, lines 6-8). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Goodin to those of Miraki in order to increase the rigidity of the proximal end of the catheter, thereby providing additional support to the proximal end of the catheter.

In regards to claim 9, Miraki indirectly teaches that the lumen of the catheter [32] has a first cross-sectional area and the stiffening member [12] has a second cross-sectional area, the second cross-sectional area being less than the first cross-sectional area, since the stiffening member is positioned within the catheter (Figures 5-7). The positioning of the stiffening member with respect to the catheter permits an inflation fluid to flow through the lumen between the connector [118] on the proximal end portion of the catheter and the interior volume of the balloon [132] (column 8, lines 50-56)(column 10, lines 53-60).

In regards to claim 10, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon, the distal end comprising a port (bore [36]) to permit the inflation fluid to flow between the lumen of the catheter and the interior volume of the balloon [132] (Figure 6).

In regards to claim 21, Miraki teaches that the stiffening member (wire-like shaft [18] of guide wire assembly [12]) comprises a solid wire having a circular cross-section, as can be seen in Figures 6-7 (column 6, lines 6-9).

In regards to claim 22, Miraki does not teach that the stiffening member comprises a lumen. Goodin teaches a stiffening member (inner tube [22]) that has a guidewire lumen extending therethrough (Figures 1-2) (column 2, lines 47-50). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the stiffening member of Miraki with a guidewire lumen, as taught by Goodin, as such will allow for the proper placement of a catheter within a blood vessel based on the initial positioning of the guidewire within the blood vessel at the treatment site (column 1, lines 14-20).

In regards to claims 23 and 25, Miraki teaches that the stiffening member [12] has a tapered cross-section at its tapered portion [28], distal to its wire-like shaft portion [18], which has a larger outer diameter than the tapered portion [28] (Figure 6). Therefore, the stiffening member [12] has a first physical property (*outer diameter*) at a first location (*wire-like shaft portion [18]*) and a second physical property (*outer diameter*) at a second location (*tapered portion [28]*), wherein the two physical properties are different since the outer diameter of the portion [18] is larger than the outer diameter of the portion [28].

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 9 above, and further in view of Hamilton et al (US 6,514,228).

In regards to claim 11, Miraki teaches that the distal end portion of the catheter [32] comprises a distal end that terminates within the interior volume of the balloon; however, Miraki does not teach that said distal end is fixedly connected to the stiffening member, since the stiffening member is slidable within the catheter (Figure 6 to Figure 7). Hamilton et al teaches a balloon catheter (Figure 4, balloon catheter [40]) in which a transition tube [46] sealingly

connects the distal end of a catheter (shaft [42]) to a stiffening member (tip tube [44]) (column 5, lines 55-57). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the teachings of Hamilton et al to the modified device of Miraki by providing a transition tube between the distal end of the catheter and the stiffening member as the transition tube provides a fluid connection between the distal end of the catheter and the stiffening member (column 5, lines 52-55).

18. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, as applied to claim 13 above, and further in view of Ryan et al (US 5,108,416).

In regards to claim 18, Miraki does not teach that the distal end of the balloon comprises an end cap affixed thereto with the sleeve being defined by an interior volume of the end cap. Ryan et al teaches a balloon catheter in which an end cap [28] (Figure 7A) at the distal end of a balloon [20] surrounds a sleeve (mounting sleeve [38]) (column 6, lines 26-28). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the end cap of Ryan et al to the distal end of the balloon of Miraki because Ryan et al teaches that the end cap will prevent the sleeve from detaching from the catheter shaft if compression forces are applied at the distal end of the balloon (column 6, lines 19-21).

19. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki, as applied to claim 19 above, and further in view of Hernandez et al (US 5,269,759).

In regards to claim 20, Miraki teaches that the connector [118] comprises a female luer fitting [122] (Figure 5); however, Miraki is silent about whether inflation device that is

connected to the fitting is a syringe. As illustrated by Hernandez et al, it is common practice in the art to administer fluid via a syringe: Hernandez et al teaches a balloon catheter [14] (Figure 1) onto which a syringe is connected at a at side port [17], having a luer fitting, in order to force inflation fluid under pressure to inflate the balloon [16] of the catheter (column 5, lines 45-52). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to use the syringe as taught by Hernandez et al as the inflation device to inflate the balloon of the catheter of Miraki, as such will allow inflation fluid to be forced under pressure to inflate the balloon (column 5, lines 45-52).

20. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miraki and Goodin, as applied to claim 23 above, and further in view of Swanson (US 5,605,543).

In regards to claim 24, Miraki is silent about whether the first physical property of the stiffening member is a first stiffness and the second physical property of the stiffening member is a second stiffness, the first stiffness being greater than the second stiffness. Swanson teaches a balloon catheter [10] (Figure 1) with a guidewire tube [20] composed of a proximal guidewire tube [21] and a distal guidewire tube [22], with the proximal guidewire tube being stiffer than the distal guidewire tube (column 4, lines 43-52). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply the varying stiffness properties of the stiffening member taught by Swanson to the two portions of the stiffening member of Miraki in order to enhance pushability of the resultant catheter since the proximal end is stiffer than the distal end (column 4, lines 53-55).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571)270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
04/21/2008

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764